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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,268	03/18/2004	Arnold C. Takemoto	ATAKEM-003-USA	7455

7590  
GREGORY SHEN  
4959 Lorraine Drive  
San Diego, CA 92115

08/27/2007

EXAMINER
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MAEWALL, SNIGDHA

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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08/27/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/804,268	Applicant(s) TAKEMOTO, ARNOLD C.	
	Examiner Snigdha Maewall	Art Unit 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____                                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____   | 6) <input type="checkbox"/> Other: ____                           |

## DETAILED ACTION

### *Summary*

1. Applicant is reminded that the office has not received IDS as of this date.

Claim 1 is pending in this application and claim 1 will be prosecuted on the merits.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "derivatives of alpha-lipoic acid". The claim is indefinite because the metes and bounds of the claim cannot be defined. It is not clear which compounds are included and which aren't.

Claim 1 recites, "atleast 1% of said one or more members from said first/ second/third group is in microspheres", however, the claim does not disclose the total weight of the preparation. In the absence of such, the claim renders itself indefinite. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable Kochendoerfer et al. (US Pub. No. 2003/0018169 A1) in view of Huang (US Pub No. 2004/0204344 A1).

Kochendoerfer et al. discloses an invention relating to methods and compositions for lipid matrix assisted chemical ligation and synthesis of membrane polypeptides (abstract). Example 1 depicts preparation of lipid vesicles where egg –Lecithin is dissolved in 2:1 chloroform/methanol, evaporated and dissolved in EDTA (see page 25, example 9) and further pelleted as liposomes.

Kochendoerfer et al does teach chelating agent such as alpha –lipoic acid.

Huang teaches alpha lipoic acid as contrast imaging agents and its use in detecting the presence of amyloid deposits by imaging technologies and thus preventing or treating amyloid related conditions, such as Alzheimer's disease (abstract and page 9, paragraph [0108]). On page 9, paragraph [0108], Huang discloses that alpha-lipoic acid derivatives is used as metal chelating agent and as an antioxidant. Furthermore, paragraph [0010] discloses( by referring to US Patent 6,323,218) that metal chelating

compounds such as EDTA is described as therapeutics for the treatment of pathological conditions associated with amyloidosis. It is further disclosed that Alpha lipoic acid can be prepared in the form of liposome (see paragraph [0197].

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate alpha-lipoic acid in the composition and method forwarded by Kochendoerfer et al. because of alpha-lipoic acid's use as metal chelating agent and treatment of conditions associated with amyloids. A skilled artisan would thus have been motivated to prepare an encapsulated bioavailable chelating agents comprising Lecithin, EDTA and Alpha-Lipoic acid with a reasonable expectation of success. With regard to the percentage of the components, it is the position of the examiner that such parameters can be optimized. Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

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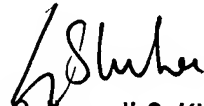
number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

Art Unit

1615

  
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